

FILED  
U.S. DISTRICT COURT  
DISTRICT OF WYOMING

JUL 21 2010

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Cheyenne

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ATTORNEYS FOR PLAINTIFFS

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF WYOMING**

CODY LABORATORIES, INC., a Wyoming  
corporation, and LANNETT CO., INC., a  
Delaware corporation,

Plaintiffs,

v.

THE HONORABLE KATHLEEN SEBELIUS,  
SECRETARY, U.S. Department of Health and  
Human Services, and DR. MARGARET A.  
HAMBURG, COMMISSIONER, U.S. Food and  
Drug Administration,

Defendants.

Civil Action No.

**10CV0147**

**PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY  
INJUNCTION**

Plaintiffs Cody Laboratories, Inc., and Lannett Co., Inc., (collectively “Cody/Lannett”) through undersigned counsel move, pursuant to Fed. R. Civ. P. 65(a) and (b), for a Temporary Restraining Order and/or Preliminary Injunction as more fully set forth in the Memorandum in Support of Plaintiffs’ Motion for Temporary Restraining Order and Preliminary Injunction (“Memorandum”) submitted herewith. As grounds for this motion, Plaintiffs rely on the arguments set forth in their Memorandum. Attorneys for the governmental defendants in this action have been informed of the filing of this motion and have informed counsel for the Plaintiffs that the government wishes to be heard.

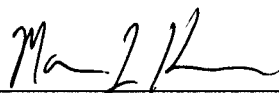
WHEREFORE, Plaintiffs Cody/Lannett request a Temporary Restraining Order and/or a Preliminary Injunction enjoining the FDA from requiring Cody/Lannett to remove Cody’s Morphine Sulfate Solution Immediate Release 20 mg/ml (“the Product”) from the market as of July 24, 2010 if such removal is based on the U.S. Food and Drug Administration’s (“FDA’s”) contention that the Product is an unapproved “new drug” for purposes of the Federal Food, Drug and Cosmetics Act (“FDCA”), enjoining the FDA from threatening or taking any enforcement action against Cody/Lannett’s customers<sup>1</sup> if such threat of enforcement or actual enforcement is based on the FDA’s contention that the Product is an unapproved “new drug” for purposes of the FDCA, enjoining the FDA from enforcing its April 9, 2010 warning letters to prevent Cody/Lannett from manufacturing, marketing, or selling the Product if such enforcement is

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<sup>1</sup> “Customers” as used herein includes all direct customers of Cody/Lannett including wholesalers, distributors, and pharmacies, as well as all legal downstream purchasers and patients using the product.

based on the absence of an approved New Drug Application (“NDA”) or Abbreviated NDA (“ANDA”), and further enjoining the FDA from threatening or taking any enforcement action against Cody/Lannett’s customers if such threat of enforcement or actual enforcement is based on the absence of an approved NDA or ANDA.

DATED this 21st day of July, 2010.



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